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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,729	10/22/2001	Douglas J. Jolly	20263.439 (1157.003)	3088
7590	10/03/2003		EXAMINER	
Chiron Corporation Intellectual Property - R440 P.O. Box 8097 Emeryville, CA 94662-8097				WEHBE, ANNE MARIE SABRINA
		ART UNIT	PAPER NUMBER	1632

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/001,729	JOLLY, DOUGLAS J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 2-5,8-11,14-29 and 35-46 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) 2-5, 8-11, 14-29, 35-46 are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### **Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### **Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.	6) <input type="checkbox"/> Other: ____.

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### **DETAILED ACTION**

Applicant's preliminary amendment received on 2/11/02 requested that cancellation of claims 1, 6-7, 12-13, and 30-34 and the addition of new claims 35-46. This amendment has been entered and claims 2-5, 8-11, 14-29, and 35-46 are currently pending in the instant application. Please note that while claims 2-5, 8-11, 14-29 were canceled in the parent application, 09/191,448, these claims are still pending in the instant application. As a continuation application, the instant application was filed with the original claim set, claims 1-34. Therefore, claims 2-5, 8-11, 14-29, and 35-46 are pending in the instant application.

Although claims 1, 7, and 13, upon which claims 2-5, 8-11, and 14-17 depend have been canceled, claims 2-5, 8-11, and 14-17 have been included in the election/restriction requirement below based on the recited limitations in view of the limitations of the canceled base claims.

#### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-5, 8-11, 14-17, and 43-46, drawn to methods of transducing dividing or non-dividing cells ex vivo, classified in class 435, subclass 455.
- II. Claims 18-20, drawn to methods of treating a patient having a genetic disease using transduced cells, classified in class 424, subclass 93.21.

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- III. Claim 21, drawn to methods of treating cancer using transduced cells, classified in class 424, subclass 93.21.
- IV. Claims 22-25, drawn to methods of treating infectious disease using transduced cells, classified in class 424, subclass 93.21.
- V. Claim 26, drawn to methods of treating inflammatory disease using transduced cells, classified in class 424, subclass 93.21.
- VI. Claim 27, drawn to methods of treating degenerative disease using transduced cells, classified in class 424, subclass 93.21.
- VII. Claims 28-29, drawn to methods of treating cardiovascular disease using transduced cells, classified in class 424, subclass 93.21.
- VIII. Claims 35-42, drawn to kits comprising recombinant retroviral particles, classified in classes 435 and 424, subclasses 320.1 and 199.1 respectively.

The inventions are distinct, each from the other because of the following reasons:

1) Inventions I and Inventions II-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product **or** (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the transduced cells of invention I can be used in substantially different methods, such as the use of the cells to produce protein *ex vivo*. Furthermore, there are

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numerous methods of using the transduced cells *in vivo* as evidenced by the specific uses recited in inventions II-VII.

2) Inventions II-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each encompass different disease states that are produced by different causative agents, effect different immunological parameters, and result in inhibition of different cellular functions. Furthermore, the genes of interest “useful for treating” each disease function by different modes of action, generate different immunological responses, have different modes of action, and act on different cell populations. Thus, the claims have different modes of operation, different functions and different effects.

3) Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product **or** (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the product of invention VIII can be used for materially different purposes than transducing cells *ex vivo*, such as the use of the particles to transduce cells *in vivo*. Furthermore, transduced cells and retroviral particles have substantially different structural, chemical, and biological properties and are made using different reagents and methods.

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4) Inventions II-VII and VIII are patentably distinct in that the retroviral particles can be used for substantially different methods than those listed in inventions II-VII, such as the use of the retroviral particles to directly transduce cells *in vivo*, or the use of the retroviral particles to isolate retroviral proteins, or nucleic acids *in vitro*.

This application contains claims directed to the following patentably distinct species of “genes of interest” of the claimed invention:

- a) cytokines
- b) colony stimulating factors
- c) clotting factors
- d) hormones
- e) ADA
- f) mutant HIV protein
- g) ribozymes
- h) T cell receptors
- i) apolipoprotein E
- j) tumor antigen.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for

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prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-3, 8-9, 14- 15, and 43-45 are generic for invention I; claims 18 and 20 are generic for invention II; claim 21 is generic for invention III; claim 22 is generic for invention IV; claim 26 is generic for invention V; claim 27 is generic for invention VI; claim 28 is generic for invention VII; and claims 35-37, and 39-41 are generic for invention VIII.

Applicant is advised that a reply to this requirement must include an election of an invention from the group of I-VIII above and an identification of the species from the group of a)-j) listed above that is elected for that invention consonant with this requirement. A listing of all claims readable thereon, including any claims subsequently added, is also required. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 872-9306.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

